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**FAX COVER SHEET**

FAX NUMBER TRANSMITTED TO: (571) 273-8300

To: US Patent and Trademark Office  
From: Howard Eisenberg  
Serial No.: 09/614,790  
Inventor(s): Sharon F. Kleyne  
Title: METHOD AND KIT FOR MOISTURIZING THE SURFACE OF THE EYE  
Filed: July 12, 2000  
Atty No.: HME/7982.0001  
Date: February 27, 2006

DOCUMENTS	NUMBER OF PAGES*
Transmittal Form	One
Fee Transmittal Form	One
Credit Card Payment Form (\$250)	One
Notice of Appeal	One
Pre-Appeal Brief Request for Review	One
Reasons for Pre-Appeal Brief Request for Review	Five

\* NOT COUNTING COVER SHEET. IF YOU DO NOT RECEIVE ALL PAGES, PLEASE TELEPHONE US IMMEDIATELY AT (215) 453-9237.

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PTO/SB/21 (09-04)

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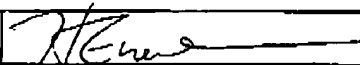
<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	09/614,780	
	Filing Date	July 12, 2000	
	First Named Inventor	Sharon F. Klayne	
	Art Unit	1817	
	Examiner Name	Wang, Shangjun	
Total Number of Pages in This Submission	10	Attorney Docket Number	HME7982.0001

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input checked="" type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Pre-Appeal Brief Request for Review (1 pg) with reasons for requested review (5 pgs)
Remarks		

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Howard Eisenberg, Esq.		
Signature			
Printed name	Howard Eisenberg		
Date	February 27, 2006	Reg. No.	36,789

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Signature			
Typed or printed name	Howard Eisenberg	Date	February 27, 2006

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PTO/SB/17 (12-04v2)

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Effective on 12/08/2004  
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4918)

# FEE TRANSMITTAL

## For FY 2005

☒ Applicant claims small entity status. See 37 CFR 1.27TOTAL AMOUNT OF PAYMENT (\$)  
250

## Complete if Known

Application Number	09/614,790
Filing Date	July 12, 2000
First Named Inventor	Sharon F. Klayne
Examiner Name	Wang, Shengjun
Art Unit	1617
Attorney Docket No.	HME/7982.001

## METHOD OF PAYMENT (check all that apply)

☐ Check ☒ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_

☐ Deposit Account Deposit Account Number: 50-1773 Deposit Account Name: Howard Eisenberg

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

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## FEE CALCULATION

## 1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

## 2. EXCESS CLAIM FEES

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180
<b>Total Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>
9 - 20 or 43 =	0	25
HP = highest number of total claims paid for, if greater than 20.		
<b>Indep. Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>
1 - 3 or 5 =	0	100
HP = highest number of independent claims paid for, if greater than 3.		
		<b>Fee Paid (\$)</b>
		0
		<b>Multiple Dependent Claims</b>
		Fee (\$)
		Fee Paid (\$)
		0

## 3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
100	0	0	0	0

## 4. OTHER FEE(S)

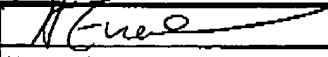
Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): Notice of Appeal

Fees Paid (\$)

250

## SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 36,789	Telephone (215) 453-9237
Name (Print/Type)	Howard Eisenberg	Date February 27, 2006	

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Doc Code: AP.PRE.REQ

PTO/SB/33 (07-06)

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<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional) <u>HME/7982.001</u>	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1460, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>FEBRUARY 27, 2006</u> Signature <u>HE</u> Typed or printed name <u>HOWARD EISENBERG</u>		Application Number <u>09/614,790</u>	Filed <u>7/12/2000</u>
		First Named Inventor <u>SHARON F. KLEYNE</u>	
		Art Unit <u>1617</u>	Examiner <u>WANG, SHENG JUN</u>
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.  This request is being filed with a notice of appeal.  The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.			
I am the <input type="checkbox"/> applicant/inventor. <input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) <input checked="" type="checkbox"/> attorney or agent of record. <u>36,789</u> Registration number <input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____		Signature <u>HOWARD EISENBERG</u> Typed or printed name <u>215-453-9237</u> Telephone number <u>2/27/2006</u> Date	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.			
<input checked="" type="checkbox"/> Total of <u>1</u> forms are submitted.			

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1460, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1460, Alexandria, VA 22313-1450.

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Atty Doc. No. HME/7982.001

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE****PATENT APPLICATION EXAMINING OPERATIONS**

In re the Application of	:	
Sharon F. Kleyne	:	Group Art Unit: 1617
Serial No. 09/614,790	:	Examiner: Shengjun Wang
Filed: July 12, 2000	:	Tel. No. (571) 272-0632
For a Patent for	:	Date: February 27, 2006
METHOD AND KIT FOR MOISTURIZING THE SURFACE OF THE EYE	:	

**REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir,

In conjunction with the submission of a Pre-Appeal Brief Request for Review,  
Applicant submits the following reasons for request for review.

**REMARKS**

Claims 90-93 and 97-101 have been finally rejected in an Office Action mailed on November 30, 2005. As called for in independent claim 90, each of the rejected claims calls for a method for moisturizing the eye, which method comprises (1) spraying a mist consisting essentially of droplets of water (2) having an average diameter between 5 and 150 microns on the surface of the eye of a subject in need thereof, (3) wherein the amount of water that is sprayed on

the eye is (3a) sufficient to hydrate the aqueous layer of the tear film on the eye of the subject but is (3b) below that which will wash away the tear film, and (4) wherein the mist is sprayed from a device comprising a (4a) sealed container, (4b) water within said container, and (4c) an actuator for spraying a mist of water from said container, and (5) wherein the water is sprayed on the surface of the eye within a period of 10 seconds.

The Examiner has rejected all pending claims as being obvious under 35 U.S.C. §103(a) over the combined disclosures of Junkel, U.S. Patent No. 5,620,633; Hahn, U.S. Patent No. 5,893,515; Hutson, U.S. Patent No. 5,588,564, and Embleton et al (WO 97/23177).

Applicant submits that the Examiner has failed to make a prima facie case of obviousness.

Applicant has presented arguments that refute the finding of obviousness in an Amendment filed on September 6, 2005. The prior art, taken individually or in combination, does not suggest the features of the present invention.

The primary reference, Junkel, U.S. Patent No. 5,620,633, has nothing to do with moisturizing the eye but rather discloses a misting device for cooling the body of one suffering from heat or dehydration due to sun exposure or sweating due to athletic endeavors. Junkel does not disclose applying the mist to the face or to a subject in need of moisturizing the eye.

Hahn, U.S. Patent No. 5,893,515 discloses an apparatus for applying a mist of a comfort liquid or drug to the eye. Hahn does not disclose administering water to the surface of the eye. Rather, Hahn refers to moistening liquids, comfort liquids, eye drop liquids, or liquid medium. Applicant has previously submitted two Declarations, one by Dr. Rachael Garrett on December 18, 2001, who testified that "Artificial tears, dry eye therapies, and comfort drops

contain ingredients other than water that are essential for their beneficial effects”, and one by Dr. Philip Paden on January 21, 2004, who testified that the use of water as a moisturizing agent for the eye represents a significant departure from previously accepted doctrines in the field of ophthalmology.

Additionally, Hahn discloses that the amount of comfort liquid that is to be administered to the eye is “a sufficient amount of comfort liquid or drug to saturate the eye without overflowing - about one drop.” Applicant submits that this is a teaching away from the present invention, which calls for an amount that will not wash away the tear film of the eye. As disclosed in the present specification on page 2, a drop has a volume of about 20 to 25  $\mu$ l which is sufficient to flood the eye and to wash away the tear film and replace it with the fluid that comprises the drop. This flooding the eye and washing away the tear film occurs even without overflowing the eye. Thus, the volume prescribed by Hahn is in direct contrast to that called for in the present claims.

Hutson, U.S. Patent No. 5,588,564, discloses an apparatus for providing a mist of a liquid to the surface of the eye. Hutson, like Hahn, does not disclose the administration of water as a moisturizing agent for the surface of the eye. Rather, Hutson discloses the delivery of “a fluid” (see Abstract, and column 2, line 6), an “eye wash solution” (see column 1, line 51), or “an eye solution mist” (see column 1, line 65). Additionally, Hutson is silent as to the volume of liquid that is dispensed to the eye.

Embleton et al (WO 97/23177) has been discussed in several past amendments filed on July 9, 2001, January 9, 2002, July 25, 2002, and December 9, 2004. Embleton teaches away from the present invention which calls for spraying a mist as Embleton discloses the

necessity of administering the fluid as a jet or stream. Further, Embleton does not disclose the administration of water. As argued by Applicant and as testified to by Dr. Rachael Garrett in her Declaration filed on December 18, 2001, the disclosure cited by this Examiner and the previous Examiner does not refer to administration of water, but rather to administration of a treatment fluid based on water.

Accordingly, Applicant respectfully submits that the prior art does not disclose or suggest the present invention and that the Examiner has failed to establish a prima facie case of obviousness.

In addition, Applicant submits that, even if the Examiner has established prima facie obviousness of the claimed invention based on the prior art, Applicant has overcome this basis of rejection by the submission of numerous Declarations. The following Declarations have been filed which, it is submitted, are sufficient to overcome a finding of prima facie obviousness

Declaration by Dr. Philip Paden, submitted January 30, 2004, testifying that the present invention is a departure from previous accepted doctrine in ophthalmology.

Declaration by Dr. William Mathers, submitted January 30, 2004, testifying regarding unexpected advantageous properties obtained by the method of the invention.

Declaration by Dr. Darwin Liao, submitted January 30, 2004, testifying regarding unexpected advantageous properties obtained by the method of the invention.

Second Declaration by Dr. William Mathers, submitted May 10, 2005, testifying that the invention addresses and solves a long-standing unresolved problem pertaining to the treatment of patients with symptoms due to dry eyes.



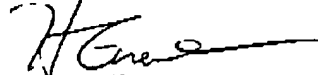
Applicant also has submitted, with the Amendment filed on January 30, 2004, an article in Exchange & Commissary News, 43(1):6 (January 15, 2004) that discloses that the U.S. military is using a commercial version of the invention and is supplying it to troops in Iraq who have found it to be superior to other products in moisturizing their eyes in that harsh desert climate. This establishes the commercial success of the invention and acceptance of the product embodying the invention by the marketplace.

Applicant submits, accordingly, that even if the prior art establishes prima facie obviousness of the invention, Applicant has submitted evidence sufficient to overcome such prima facie obviousness.

#### Conclusion

Applicant submits that the Examiner has failed to establish a case of prima facie obviousness of the present claims and, if the Examiner has established prima facie obviousness, evidence has been submitted that is sufficient to rebut the finding of prima facie obviousness.

Respectfully submitted,

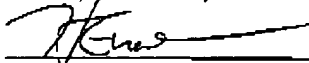


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Dated: February 27, 2006



Howard M. Eisenberg